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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,222	01/20/2004	Rolf Joachim Mehlhorn	028723-389	6448

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Bernard F. Rose
SQUIRE, SANDERS & DEMPSEY L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111-3492

EXAMINER	
WEDDINGTON, KEVIN E	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,222	MEHLHORN, ROLF JOACHIM	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *13-15 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-21-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-26 are presented for examination.

Applicant's drawings filed January 20, 2004 and the information disclosure statement filed June 21, 2007 have been received and entered.

Applicant's election filed September 5, 2007 in response to the restriction requirement of June 5, 2007 has been received and entered. The applicant elected the invention described in claims 1-12 (Group I) with traverse.

Applicant's traverse is noted, but is not deemed persuasive for reasons set forth in the Office action dated June 5, 2207; therefore, the restriction requirement is hereby made Final.

Claims 16-23 will be examined with the elected group.

Claims 13-15 and 24-26 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Specification

The disclosure is objected to because of the following informalities:

It contains a number of misspelled words and a number of words with the letters missing, for example, page 1, line 32, "encapsulat d". The entire disclosure contains a number of these informalities.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a

patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,762,957. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the present claims and the patented claims lie in that the present claims, an additional step is applied with the kit.

The present claims would anticipate the patented claims because the patented claims recite "comprising" and thus opens the claims to the inclusion of additional steps.

Claims 16-23 are not allowed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent

the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,827,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of loading lipid-like vesicles having a membrane permeable to a chemical species to be loaded form a loading solution, etc... , and the patented application teaches a method of preparing a liposome-entrapped ionizable phosphorylated hydrophobic compound (a lipid-like vesicle) with a solution also. Clearly, both the present application encompasses the patented application's specific lipid-like vesicle.

Claims 1-12 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain a number of errors and words missing letters.

Corrections are required.

Claims 1-12 and 16-23 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nichols et al., Biochimica et Biophyscia Acta 455, pp. 269-271 (1976) or C46 of PTO-1449.

Nichols et al. teach a method of preparation of liposomes using instant method (note the entire publication, page 270 in particular). The drugs loaded include epinephrine (page 271). The method involves preparing liposomes with acidic pH and titrating them with a base to create a pH gradient and adding a basic drug such as epinephrine to load the drug.

Claim 1 is not allowed.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipate by Deamer et al., Biochimca et Biophysica Acta 274, pp. 323-335 (1972) or C15 of PTO-1449.

Deamer et al. teach a method of preparation of liposomes using instant method (note entire publication , page 270 in particular). The compounds loaded include amines (note abstract and Method section). The method involves preparing liposomes with acidic pH and titrating them with a base to create pH gradient and adding a basic amine.

Claim 1 is not allowed.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cramer et al., Biochem and Biophys Research Communications 75, No. 2, pp. 295-301 (1977) or C& of PTO-892.

Cramer et al. teach a method of loading substance using pH gradient (note the abstract). The method involves the preparation of liposomes and lowering the pH of the external medium. The compounds loaded are acidic in nature (note the abstract and Materials and methods).

Claim 1 is not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. or Deamer et al. or Cramer et al.

Nichols et al. and Deamer et al. do not teach the establishment of the pH gradient by the addition of an acid. It is deemed, however, to be within the skill of the art of chemistry that if the internal medium is basic one can only establish a gradient by the addition of an acidic substance (that is, altering the pH). Nichols et al. and Deamer et al. teach the concept of loading a chemical species into the liposomes using a pH gradient. I would have been obvious to one of ordinary skill in the art to load any drug with the expectation of similar loading since Nichols et al. and Deamer et al. teach the principle of loading.

Cramer et al. do not teach the establishment of the pH gradient by the addition of an acid. It is deemed, however, to be within the skill of the art of chemistry that if the internal medium is basic one can only establish a gradient by the addition of an acidic substance (that is, altering the pH). Cramer et al. teach the concept of loading a chemical species into the liposomes using a pH gradient. I would

have been obvious to one of ordinary skill in the art to load any drug with the expectation of similar loading since Cramer et al. teach the principle of loading.

Claims 1-12 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
November 25, 2007